

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

MDL No. 19-2875 (RBK/KW)

This document relates to:
All Actions

**SPECIAL MASTER ORDER NO. 3
REGARDING AUROBINDO STANDARD OPERATING PROCEDURES**

Upon consideration of Plaintiffs' requests made during the February 17, 2021 Discovery Conference that all Standard Operating Procedures, defined to include internal procedures and protocols, however titled ("SOP's"), and indexes or lists thereof, responsive to Plaintiffs' Requests for Production be produced by Aurobindo,

It is hereby ORDERED this 18th day of February, 2021 that the following be done within 14 days of the entry of this Order:

1. Aurobindo shall supplement its production to ensure all versions of all SOPs responsive to Plaintiffs' Requests for Production have been produced from all Aurobindo entities.

2. This includes but is not limited to the production of SOPs covering the following topics:

- a. Procurement or purchase of solvents or recovered solvents, including from Lantech;
 - b. Audits or other due diligence, both before purchasing solvents/recovered solvents and after purchase, inclusive of any testing done on the product, and audits of the seller's facilities or processes;
 - c. Testing or validation protocols in connection with the use of solvents or recovered solvents;
 - d. Risk assessment for manufacturing processes, chemical interactions, change control, quality or purity, and use of solvents/recovered solvents;
 - e. Standard Testing Procedures for solvents or recovered solvents;
 - f. Any other SOPs that address manufacturing, process validation, specifications, testing, safety, quality, purity, and use of solvents and recovered solvents, including with reference to good manufacturing practices.
3. Upon completing its supplemental production, Aurobindo shall serve a certification upon Plaintiffs certifying that it has complied with this Order.

s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master